

VIA ELECTRONIC FILING

RESPONSE TO RESTRICTION REQUIREMENT Address to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Docket No.	HANO-001
	Application No.	10/521,669
	Confirmation No.	9231
	Filing Date	November 8, 2005
	Examiner	Palenik, Jeffrey T
	Group Art Unit	1615

Sir:

This communication is submitted in response to the Restriction Requirement dated April 22, 2008. The Examiner therein required election of one of the following groups of claims:

Group I: Claims 1, 5, 6, 10-13, 16, 27, 72 and 73, drawn to a paclitaxel composition;

Group II: Claims 28-30, drawn to a method of manufacturing the composition of Group I;

Group III: Claims 31 and 32, drawn to a method of manufacturing the composition of Group I;

Group IV: Claims 3, 37, 38, 42, 43, 48-51, 65 and 74, drawn to a paclitaxel composition with an emulsifier;

Group V: Claims 66-69, drawn to a method of manufacturing the composition of Group III; or

Group VI: Claims 70 and 71, drawn to a method of manufacturing the composition of Group III.

The Applicants hereby elect to prosecute the claims of Group I, claims 1, 5, 6, 10-13, 16, 27, 72 and 73 drawn to a paclitaxel composition, with traverse.

In response to the Election of Species Requirement applicants make the following elections.

With respect to the Election regarding claim 11 applicants elect the "insoluble drugs."

With respect to the type of insoluble drug as per claim 12 applicants elect “anti-cancer drugs.”

With respect to the specific insoluble drug as per claim 13 applicants elect the “paclitaxel derivatives.”

Neither the Restriction Requirement or the Election of Species Requirement were entirely clear to applicants. However, a sincere effort has been made to respond. If, for any reason, the Examiner does not consider the response to be complete the Examiner is requested to contact the undersigned attorney at the indicated telephone number to arrange for an interview to discuss the matter.

Applicants make all of the elections with traverse. Applicants point out that Groups I-VI do share a common technical feature in terms of using specific percentage amounts of monoolein, oil and paclitaxel as essential constituents. In accordance with applicants’ formulation it is not necessary to use diglyceride as is used in U.S. Patent 6,531,139. In view of such it is applicants’ position that the groups should be joined and examined together.

On page 6 of the Office Action it is argued that U.S. Patent 6,531,139 teaches a composition comprising a monoolein, an oil and paclitaxel. It appears as though the ‘139 patent discloses a pharmaceutical composition comprising a lipophilic, a pharmaceutically active agent and a mixture of diglyceride and monoglyceride in a specific ratio of 9:1 to about 6:4 by weight of the diglyceride:monoglyceride. The ‘139 patent emphasizes the use of a diglyceride as well as a monoglyceride in a specific ratio. Thus, the diglyceride is an essential constituent of the formulation taught in the ‘139 patent. However, applicants’ formulation does not use a diglyceride and applicants teach a specific amounts of monoolein, oil and paclitaxel which are not taught within the ‘139 patent. Thus, it is applicants’ position that the Restriction Requirement should be reconsidered and withdrawn at least in part because the Restriction Requirement is based , at least in part, on an incorrect assumption with respect to differences between the claimed invention and the ‘139 patent.

As stated in the MPEP §803, if search and examination of an entire application can be made without serious burden, the examiner must examine the entire application on the merits, even though the entire application includes claims to independent or distinct inventions. It is the Applicants' position that it would not be unduly burdensome to perform a search on all of the claims together in the present application. Accordingly, the Applicants traverse the restriction requirement.

The Applicants expressly reserve the right under 35 USC §121 to file a divisional application directed to the non-elected subject matter or any subject matter disclosed in this application during the pendency of this application.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815, order number HANO-001.

Respectfully submitted,

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By: _____

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